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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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| 09/874,580 | 06/05/2001 | Richard A. Brauckman | TGXX-1003US | 6921 |

21302 7590 10/07/2002

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EXAMINER

WEBB, SARAH K

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| ART UNIT | PAPER NUMBER |
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3731

DATE MAILED: 10/07/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/874,580

Applicant(s)

BRAUCKMAN ET AL.

Examiner

Sarah K Webb

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 05 June 2001.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-35 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-35 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 4,5.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other:

DETAILED ACTION

Claim Objections

1. Claims 30 and 31 are objected to because of the following informalities: they recite the limitation "the radioactive material is palladium-103", while the independent claim (26) only says that the material can be a radioactive or a drug. Examiner suggests claiming *the material is radioactive* before claiming *the radioactive material is palladium*. Appropriate correction is required.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

2. Claim 35 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. It is unclear whether applicant is claiming structure of the stent, the step of conforming the foil sheet, or the step of expanding an internal support.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in-

(1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effect under this subsection of a national application published under section 122(b) only if the international application designating the United States was published under Article 21(2)(a) of such treaty in the English language; or

(2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that a patent shall not be deemed filed in the United States for the purposes of this subsection based on the filing of an international application filed under the treaty defined in section 351(a).

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3. Claims 1-35 are rejected under 35 U.S.C. 102(e) as being anticipated by U.S. Patent No. 6,261,320 to Tam et al.

The stent of Tam includes all the limitations of the claimed invention. Figure 20C shows the many layers that form the rolled foil stent structure. *"The term 'coating' is intended to cover generically any form of material which is ...adjacent the surface of the stent, such as a jacket or thin film..."* (column 20, paragraph 3). The inner most layer (310) is the flexible stent. The radioactive film (312) can have palladium 103 isotopes (column 22, line 26) and is located on the outer diameter of the stent (310). The radioactive film can also include a coating (311 or 314) on one side, which can be titanium (col 22, line 61- col 23, line 3). The stent layer (310) supports the coating layers (311 and 312) and forces the coating to expand as it expands.

Tam explains that the coatings can contain drugs, such as heparin, and can be bioabsorbable (column 20, paragraph 4). Figure 14 shows tabs (190) protruding from the outer layer of the device that provide mechanical attachment for securing the stent in the treatment site. Tam further explains that cyanoacrylate, or adhesive, can be applied as a coating (column 30). The sheets further include perforations (Figures 2, 4, 5) which form a mesh or screen structure. Tam explains that no unwanted isotopes are formed in the radioactive coating (column 26, line 23), so the palladium-103 would be carrier free.

Figures 1,7,9,10, and 12 show the stent, as described above, delivered by an insertion device, or catheter (120).

Conclusion

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

- US Patent No. 6,193,746 to Strecker – lining for a stent that unfolds as it expands, biodegradable, mesh structure, medications included.
- US Patent No. 6,287, 249 to Tam et al. – radioactive thin film, used with stent implantation, Pd-103, heparin, method of implanting.
- US Patent No. 6,447,439 to Vallana et al. – coiled sheet stent, mesh structure, radioactive agents,
- US Patent No. 6,293,899 to Sioshansi et al. – material formed of rhodium, includes palladium-103. Can be a sheet, coiled, mesh or screen form, implantable device
- US Patent No 6,149,574 to Trauthen et al. – thin radioactive film, includes Palladium-103, used with stent delivery

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sarah K Webb whose telephone number is (703) 305-7554. The examiner can normally be reached on 8am-4:30pm Mon-Fri.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Milano can be reached on 703-308-2496. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 305-3590 for regular communications and (703) 305-3590 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0858.

Sarah K Webb
Examiner
Art Unit 3731

SW
September 30, 2002



Michael Milano
Supervisory Patent Examiner
Art Unit 3700